EPCglobal Update

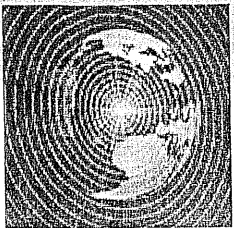## State of Pedigree and EPC/RFID Standards

California Board of Pharmacy

April 18, 2007

Mike Rose, Tri-Chair, EPCglobal HLS IAG
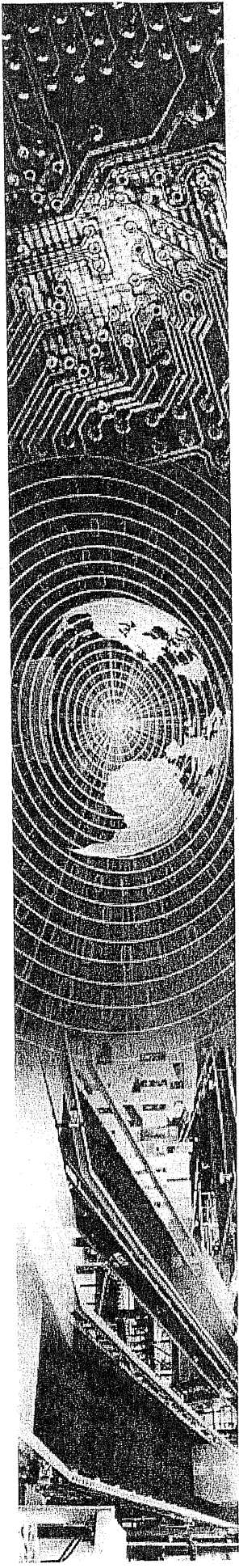
Ron Bone, Tri-Chair, EPCglobal HLS IAG

Bob Celeste, EPCglobal North America
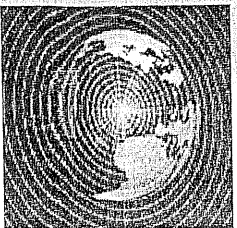
GS1 EPCglobal

Overview

- State of the Standards

- Brief Pedigree Overview
  - Structure
  - Business Scenarios

- Pedigree Review Follow-Up Items

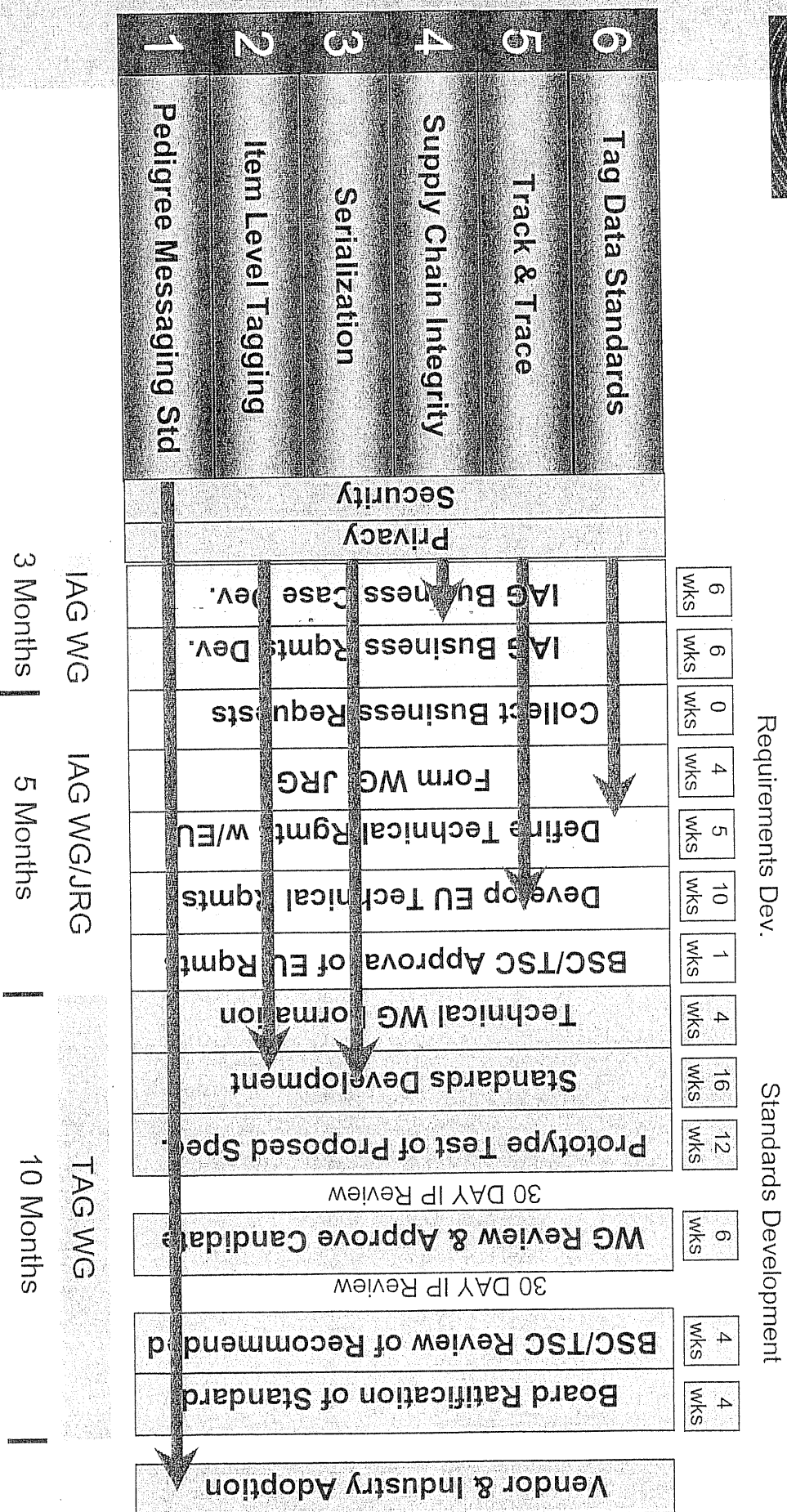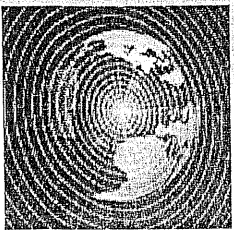GS1 EPCglobal

EPCglobal Healthcare Standards

GS1 EPCglobal

Standards Update

Standards Update

1	Pedigree Messaging Std
2	Item Level Tagging
3	Serialization
4	Supply Chain Integrity
5	Track & Trace
6	Tag Data Standard

Define a standard format for a Pedigree Messaging standard that will meet all current Federal and State Pedigree requirements.

Status:

- All Standards work complete.
- **Ratified standard – 01/2007**
- Certification Program underway
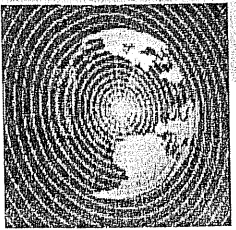
5

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Standards Update

6	Tag Data Standard
5	Track & Trace
4	Supply Chain Integrity
3	Serialization
2	Item Level Tagging
1	Pedigree Messaging Std

Define requirements for tagging pharmaceuticals at the item level. Include requirements for manufacturing lines, distribution environments, transportation and Retail environment.

Status:

- Requirements complete. Resulted in a High Frequency technical working group to define the standard.

- HF & UHF initiatives underway to provide uniform air interface protocol at item level.

- HF Standard expected '07.
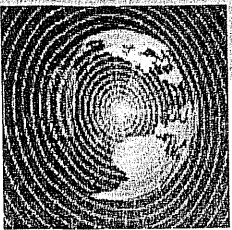
6

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Standards Update

1	Pedigree Messaging Std
2	Item Level Tagging
3	Serialization
4	Supply Chain Integrity
5	Track & Trace
6	Tag Data Standard

Define requirements for the EPC identifier to be encoded on an RFID tag.

Status:

- Requirements complete. Identified 2 GS1 identifiers [Global Trade Item Number (GTIN) and Serialized Shipping Container Number (SSCC)] to be used.

- Collaborating with GS1/HUG via the "Global Healthcare Initiative" — starting with Serialization.

  - Joint HUG/HLS Work Team
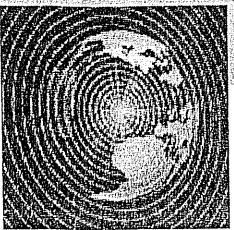
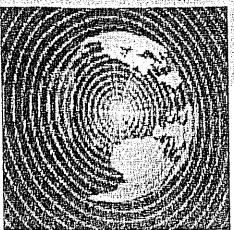GS1 EPCglobal

Standards Update

6	Tag Data Standard
5	Track & Trace
4	Supply Chain Integrity
3	Serialization
2	Item Level Tagging
1	Pedigree Messaging Std

Define requirements and/or guidelines for authenticating and decommissioning tags consistent with optimizing tag utility and consumer/patient privacy.

Status:

- Work Group has been approved and will start in March 2007

- US Drug Enforcement Agency interest in this capability is extremely high

- Solutions expected to span a mix of hardware, software and process responses
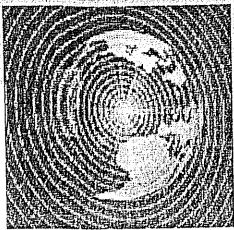
- Potential for this work to expand cross-industry

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Standards Update

6	Tag Data Standard
5	Track & Trace
4	Supply Chain Integrity
3	Serialization
2	Item Level Tagging
1	Pedigree Messaging Std

Define supply chain use cases, processes and information needs for sharing EPC related data for forward and reverse logistics.

Status:

- Forward & Reverse Logistics (Returns) processes and data exchanges completed
- Common vocabularies and location identifiers drafted
- Additional use cases to be addressed:
  - 3rd Party Logistics Providers & Repackers
  - Product Recall
- Data Sharing Strategy & Guidelines are currently being addressed
- Pedigree-on-Demand concepts being Investigated
- Integrate with GS1 Traceability efforts
- **Integrate with Pedigree Model**

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Standards Update

6	Tag Data Standards
5	Track & Trace
4	Supply Chain Integrity
3	Serialization
2	Item Level Tagging
1	Pedigree Messaging Std

Define additional user memory requirements for tags (ie. Lot Number, Expiration Date).

Status: Work underway. Defining common data structure that can be used by all industries.
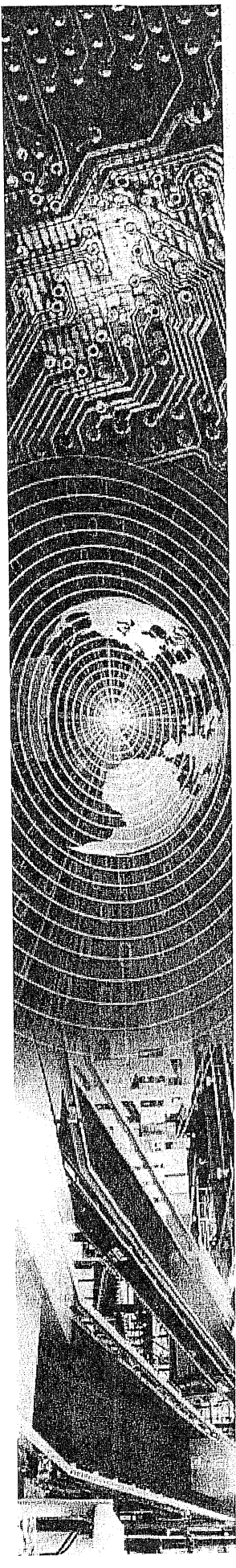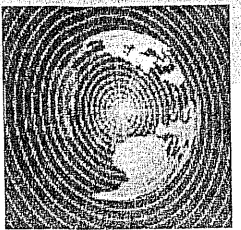
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Pedigree Messaging Standard

Post-Ratification Activities

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Pedigree Messaging Standard
Post-Ratification Activities

EPCglobal

Create Test Scripts → Create Test Platform → Create Test Guidelines → Test / Certify Pedigree Software

Pedigree Standard
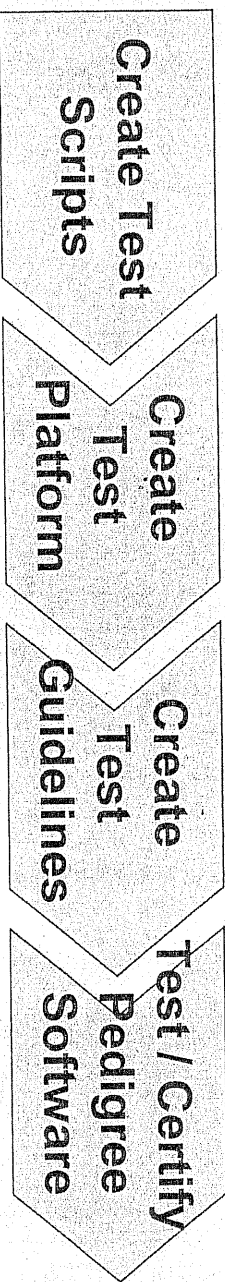
Pedigree Software — Anticipated 6/15/2007

Industry

Capital Planning → Process Re-engineering → System Integration → Infrastructure Build-out → Scale up
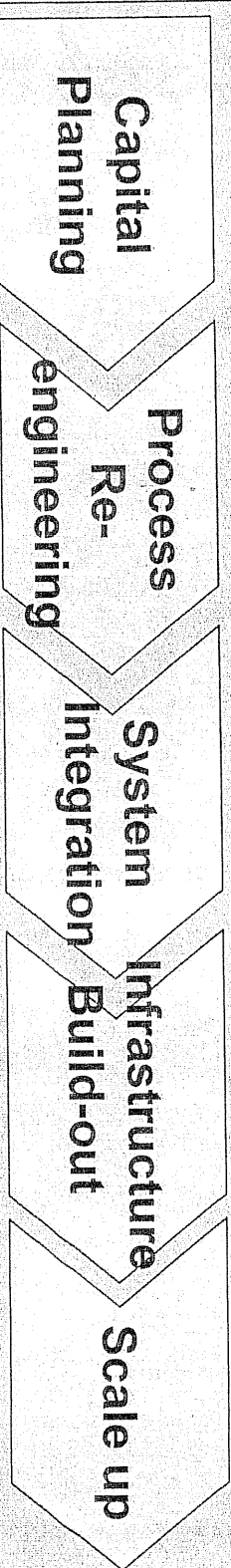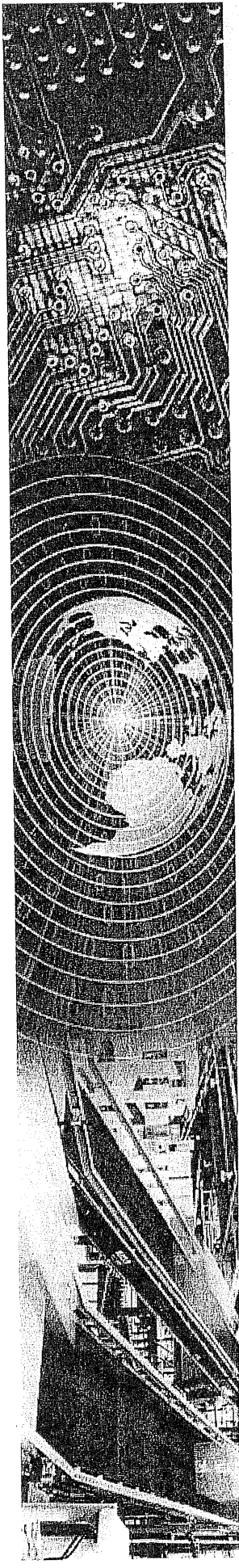
Pedigree Overview
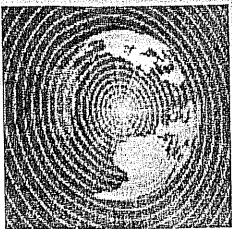
Pedigree: Participants

- Accenture
- Acsis
- Ahold USA
- Alcon Labs
- Amerisource Bergen Corp.
- Axway
- BEA Systems BMS
- Boeing
- Cardinal Health
- Cerfidia
- Cognizant Technology Solutions
- DHL, DHL Express
- Gedas Deutschland GmbH

- Glaxo Smith Kline
- GlobeRanger
- HDMA
- Hewlett Packard
- High Tech Aid
- ITRI
- Japan Telecom Co., Ltd.
- Johnson & Johnson,
- Mallinckrodt/Tyco Healthcare
- McKesson
- NCR
- NEC Corporation
- Novartis Pharmaceuticals Corp.
- P&G

- Philips Corporation
- Polaris Networks
- Raining Data Corporation
- rfXcel Corp.
- Savi Technology
- Stora Enso NBI
- SupplyScape
- ThingMagic Inc.
- TIBCO Software
- Track IT RFID Solutions
- Tyco Healthcare
- UPS SCS
- Unisys
- Verify Brand, Inc.
- VeriSign
- Walgreen Co
- Wipro

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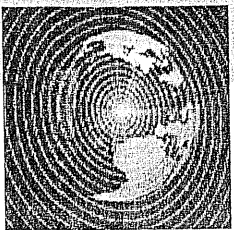
What is pedigree?

- A pedigree is a documented history of the chain of custody and/or the financial ownership of a prescription drug. Specific legislative requirements vary from state to state, but in general there are two types of information contained on the pedigree:
  - Static information about the drug - name, dosage strength, expiration date, lot #, etc.
  - The previous history of the drug - business name, date of transaction, receiving person, etc.

- Pedigree legislation implies that distributors and retailers will be required to maintain an association between the pedigree document and the physical product.

- **California Pedigree laws prohibits a DC or pharmacy from acquiring, selling, trading, or transferring a drug in that state without the accompanying pedigree. Failure to comply could result in administrative fines, revocation of license and/or criminal prosecution.**

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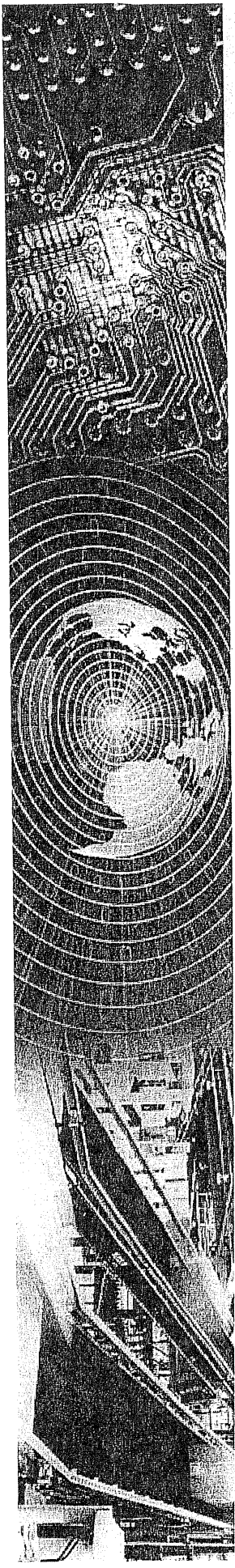
Pedigree
Requirements & Data Structure
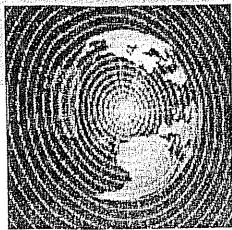
Pedigree Format Requirements

- Support for one pedigree for each individual item

- Support for a collection of items sharing the same product information (same NDC, different Lots, same chain of custody) expressed on the same pedigree

- Pedigrees for both serialized and non-serialized items

- **Representation of pedigrees in a portable format that can be transmitted electronically or via media**

  - Exchange using existing business transfer mechanisms (e.g., EDI VAN, EDI INT AS2, FTP, SOAP, etc.)

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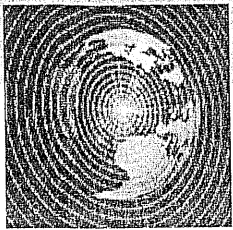
Pedigree Creation Requirements

- Pedigree initiated by manufacturer

- Pedigree initiated by wholesaler
  - With transaction information for the first wholesale distribution
  - With authentication attachment to facilitate authentication by downstream trading partners (e.g., EDI ASN)

- Pedigree initiated by repacker for a repackaged product

- Pedigree initiated by a subsequent trading partner
  - From received pedigree for next sale, transfer, or return
  - From alternate representation of pedigree (e.g., scanned paper pedigree, PDF, X.12 documents, etc.)

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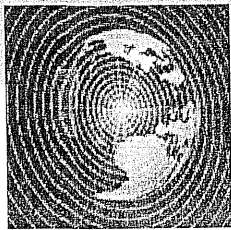
Pedigree Structure

Pedigree format: records a specific pedigree data element

- Product information, transaction information, recipient information, distributor information, and digital signatures

- Item information to describe the specific non-serialized or serialized products in the transaction

Pedigree envelope for serialized collections of pedigrees to items

- Identifying information about the envelope (to, from, date, etc.)

- Optional information about the relationship of pedigrees to items in cases to facilitate product-to-pedigree matching

- Pedigrees for the products in the shipment

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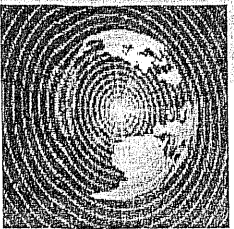
Core Pedigree Elements

Name	Description
DocumentInfo	Contains an identifier for the pedigree document.
ProductInfo	Detailed information about the product that is the subject of the pedigree, such as product name, strength, dosage form, etc.
ItemInfo	Identifies the physical item(s) associated with a pedigree by lot number, expiration date, quantity of units, and item serial numbers.
TransactionInfo	Information about a transaction in which ownership of the item passes from one supply chain partner to another, including information about the sender, recipient, business and alternate shipping addresses, transaction identifier and transaction date.
ReceivingInfo	Includes information about the receipt of items associated with a pedigree.
Signature	Expresses digital signature for shipping and receiving certifications. Includes information about the digital signature, algorithms used, properties of the certificate, properties of the certificate issuer, and the message digest.

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Core Pedigree Elements

Name	Description
ShippedPedigree	Layer of a pedigree that represents an outbound pedigree transaction. This layer is signed before it is sent.
ReceivedPedigree	Layer of a pedigree that represents an inbound pedigree transaction.
InitialPedigree	Contains the initial pedigree product information. Can include transaction and attachment information if pedigree is initiated by wholesaler. This element is also used to represent the conversion of a pedigree in another form to this pedigree format, such as a scanned or alternate representation of a pedigree that represents the prior chain of custody for the product.
RepackagedPedigree	Contains the initial pedigree information for a repackaged product before the first outbound transaction. This includes the product information for the repackaged item and pedigree information about the source items used to create the repackaged items

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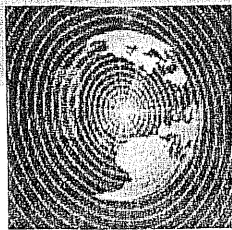
Review of Pedigree Standard
Features Supported

Feature	Required?	Support?
Item level serialization - Unique identification of each and every bottle of medication	No	Yes
Electronic Signatures - Ensures identity of Pedigree issuing company	Yes	Yes
RFID - Non Line of sight identification of Pallets, Cases or Items	No	Yes
Inference - Upon visual inspection, assuming content of containers (Pallets, Cases, Totes) based on Pedigree or Advanced Ship Notice (ASN)	No	Yes
Manufacturer initiated Pedigree - Manufacturer sends first pedigree to next participant in supply chain (as opposed to the first distributor)	No	Yes
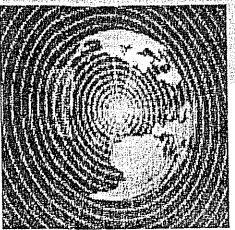
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Document Based Pedigree

Passing the Pedigree through the supply chain

Manufacturer

Wholesaler

Repackager

Provider

Return

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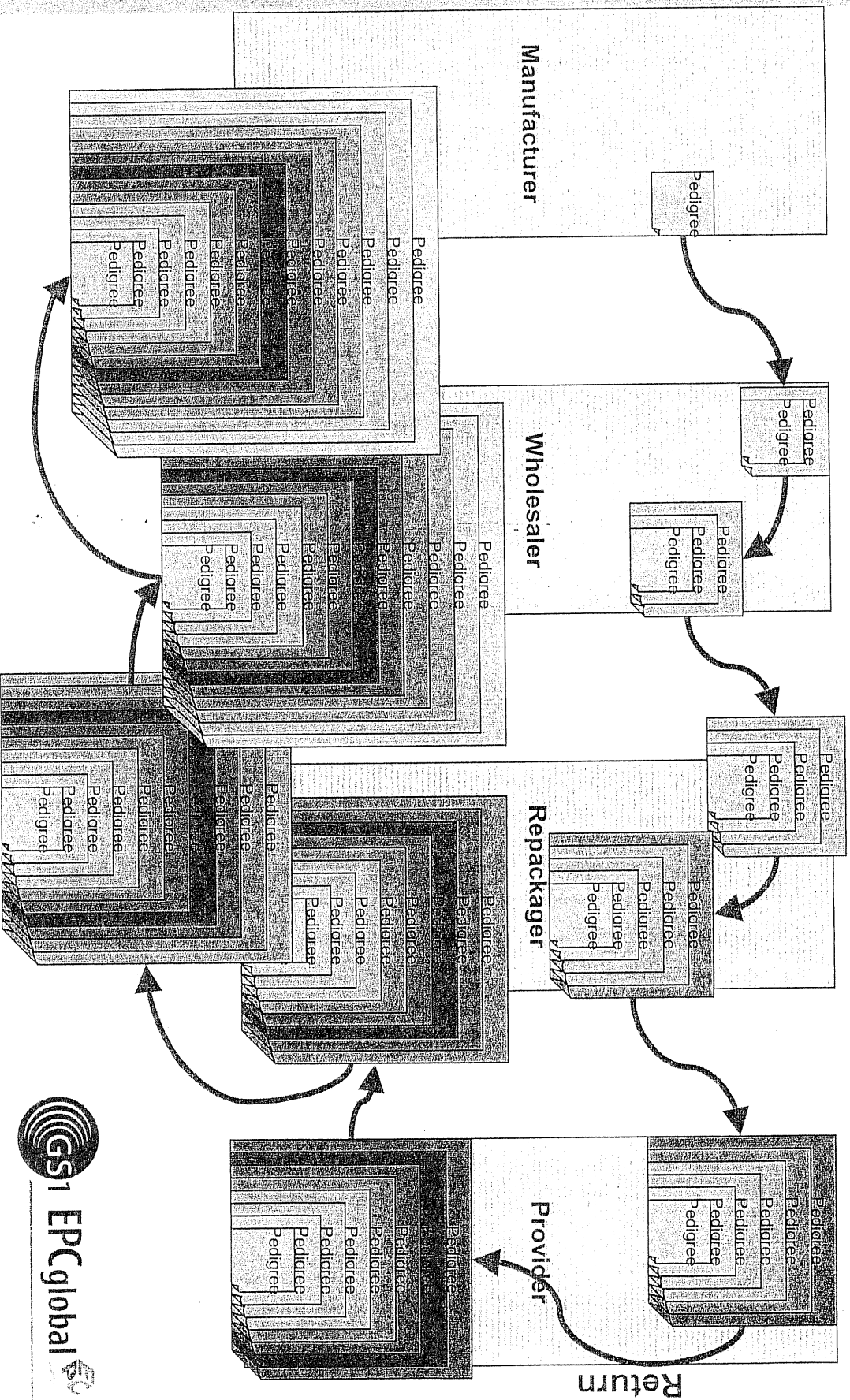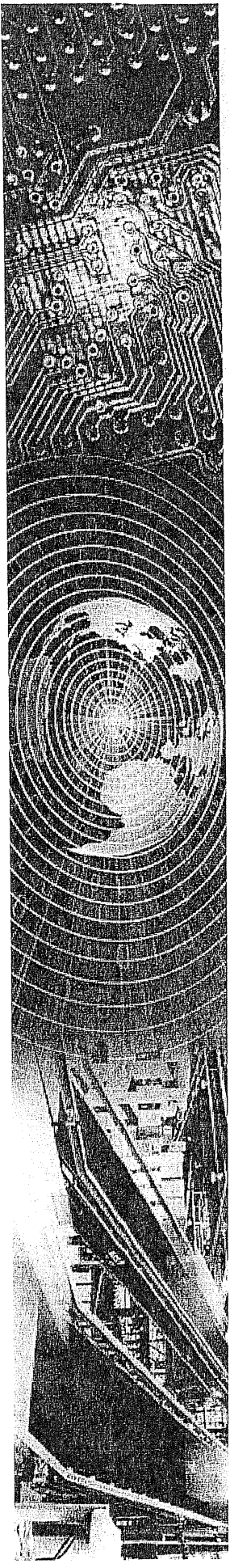
Electronic Pedigree Format

The basic components of a pedigree are shown in the following figure. The components in an actual pedigree depend on the specific business situation in which it is used (e.g., pedigree initiated by manufacturer, pedigree initiated by wholesaler, pedigree for repackaged item, etc.).

Electronic Pedigree Format

```
pedigree
  receivedPedigree id="ReceivedPed-2"
    documentInfo
    pedigree
      shippedPedigree id="ShippedPed-2"
        documentInfo
        pedigree
          receivedPedigree Id="ReceivedPed-1"
            documentInfo
            pedigree
              shippedPedigree Id="ShippedPed-1"
                docmentInfo
                initialPedigree
                  serialNumber
                  productInfo
                  itemInfo
                itemInfo
                transactionInfo
                  senderInfo
                  recipientInfo
                  transactionIdentifier
                ...
                signatureInfo
                Signature (Manuf. Signs: ShippedPed-1)
            receivingInfo
            signatureInfo
            Signature (Wholesaler Signs: ReceivedPed-1)
        itemInfo
        transactionInfo
          senderInfo
          recipientInfo
          transactionIdentifier
        ...
        signatureInfo
        Signature (Wholesaler Signs: ShippedPed-2)
    receivingInfo
    signatureInfo
    Signature (Retailer Signs: ReceivedPed-2)
```

Forms for Pedigree Components for Specific Business Situations (non-normative)

A pedigree and data components within the pedigree may take one of several forms depending on the context of how the pedigree was created or received (e.g., manufacturer initiated pedigree, wholesaler initiated pedigree, pedigree for repackaged item, conversion of alternate pedigree, etc.). The table below provides a non exhaustive list of use cases and the corresponding form a pedigree component may take for each of these use cases.
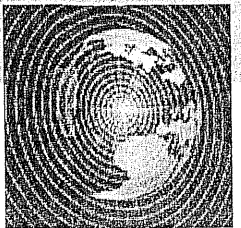
Sample Pedigree Forms

Signed manufacturer pedigree

(initiated by manufacturer, after the wholesale distribution, signed by both manufacturer and wholesaler)

```
pedigree
  receivedPedigree Id="ReceivedPed-1"
    documentInfo
      serialNumber
      version
    pedigree
      shippedPedigree Id="ShippedPed-1"
        docmentInfo
          serialNumber
          version
        initialPedigree
          serialNumber
          productInfo
          itemInfo
          itemInfo
            transactionInfo
              senderInfo
              recipientInfo
              transactionIdentifier
              ...
          signatureInfo
        Signature (Manuf. Signs: ShippedPed-1)
    receivingInfo
    signatureInfo
  Signature (Wholesaler Signs: ReceivedPed-1)
```

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Sample Pedigree F

Pedigree with return transaction

(initiated by manufacturer, received and signed inbound by wholesaler, return transaction applied by wholesaler for manufacturer return and signed outbound, received and signed inbound by manufacturer)
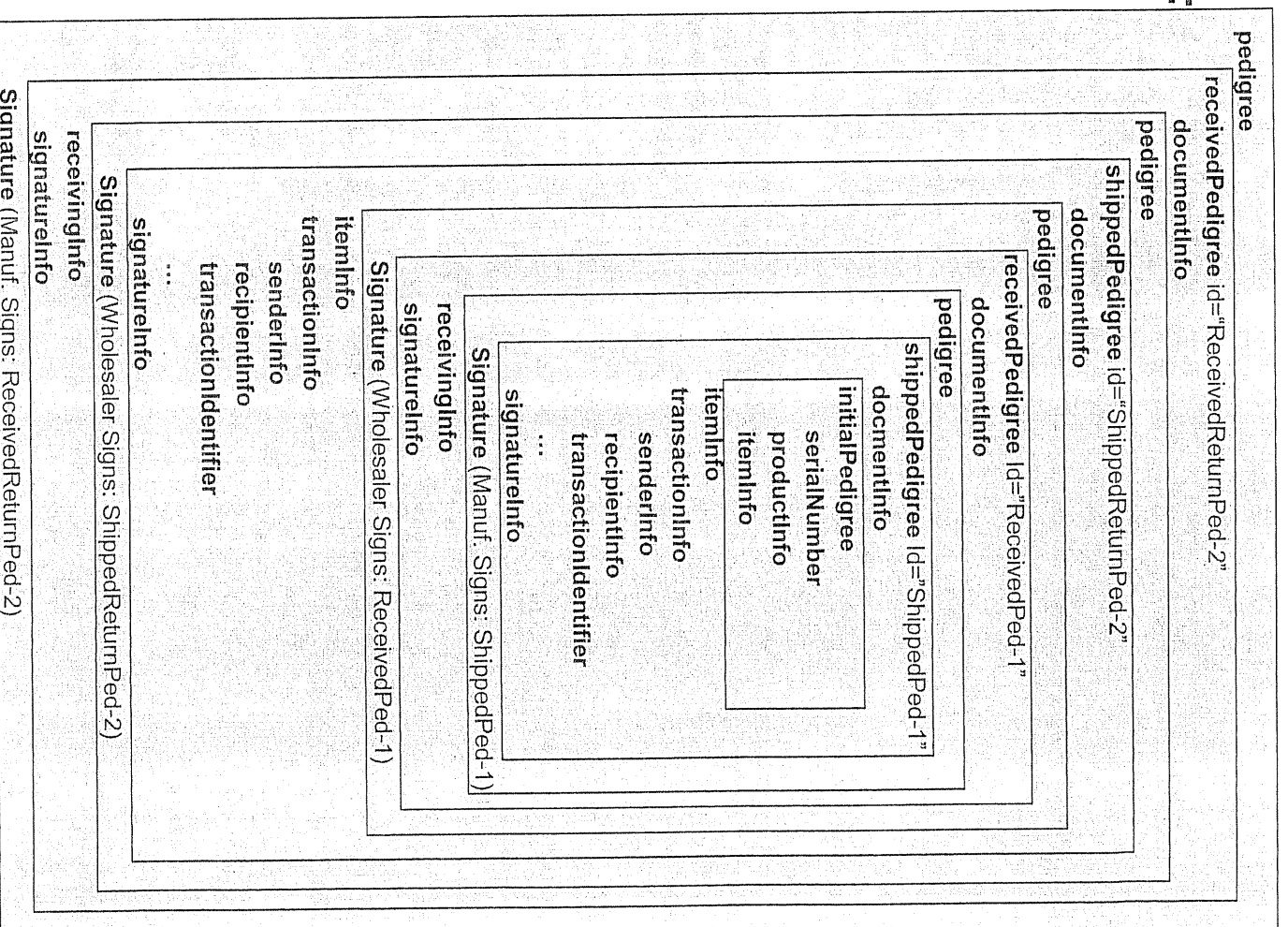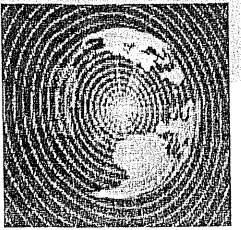
pedigree
receivedPedigree id="ReceivedReturnPed-2"
documentInfo
  pedigree
  shippedPedigree id="ShippedReturnPed-2"
  documentInfo
    pedigree
    receivedPedigree Id="ReceivedPed-1"
    documentInfo
      pedigree
      shippedPedigree Id="ShippedPed-1"
      docmentInfo
        initialPedigree
          serialNumber
          productInfo
          itemInfo
      itemInfo
      transactionInfo
        senderInfo
        recipientInfo
        transactionIdentifier
        ...
      signatureInfo
      Signature (Manuf. Signs: ShippedPed-1)
    receivingInfo
    signatureInfo
    Signature (Wholesaler Signs: ReceivedPed-1)
    itemInfo
    transactionInfo
      senderInfo
      recipientInfo
      transactionIdentifier
      ...
    signatureInfo
    Signature (Wholesaler Signs: ShippedReturnPed-2)
  receivingInfo
  signatureInfo
Signature (Manuf. Signs: ReceivedReturnPed-2)

Sample Pedigree Forms

Partial Receipt of Products against Pedigree

Partial Receipt of Products against Pedigree

The partial receipt of product against pedigree is described for a sale from a manufacturer to a wholesaler, when the manufacturer initiates the pedigree. The wholesaler receives the products in two partial shipments and updates each partial receipt against the original pedigree, resulting in a new received pedigree for each partial receipt.

First receipt for 75

Second receipt for 25

pedigree
  shippedPedigree Id="ShippedPed-1"
    docmentInfo
    initialPedigree
      serialNumber
      productInfo
      itemInfo
    itemInfo
      lot
      quantity (Qty shipped: 100)
    transactionInfo
      senderInfo
      recipientInfo
      transactionIdentifier
    ...
    signatureInfo
  Signature (Manuf. Signs: ShippedPed-1)

pedigree
  receivedPedigree Id="ReceivedPed-1a"
    documentInfo
    pedigree
      shippedPedigree Id="ShippedPed-1"
        docmentInfo
        initialPedigree
          serialNumber
          productInfo
          itemInfo
        itemInfo
          lot
          quantity (Qty shipped: 100)
        transactionInfo
          senderInfo
          recipientInfo
          transactionIdentifier
        ...
        signatureInfo
      Signature (Manuf. Signs: ShippedPed-1)
    receivingInfo
      dateReceived
      itemInfo
        lot
        quantity (Qty received: 75)
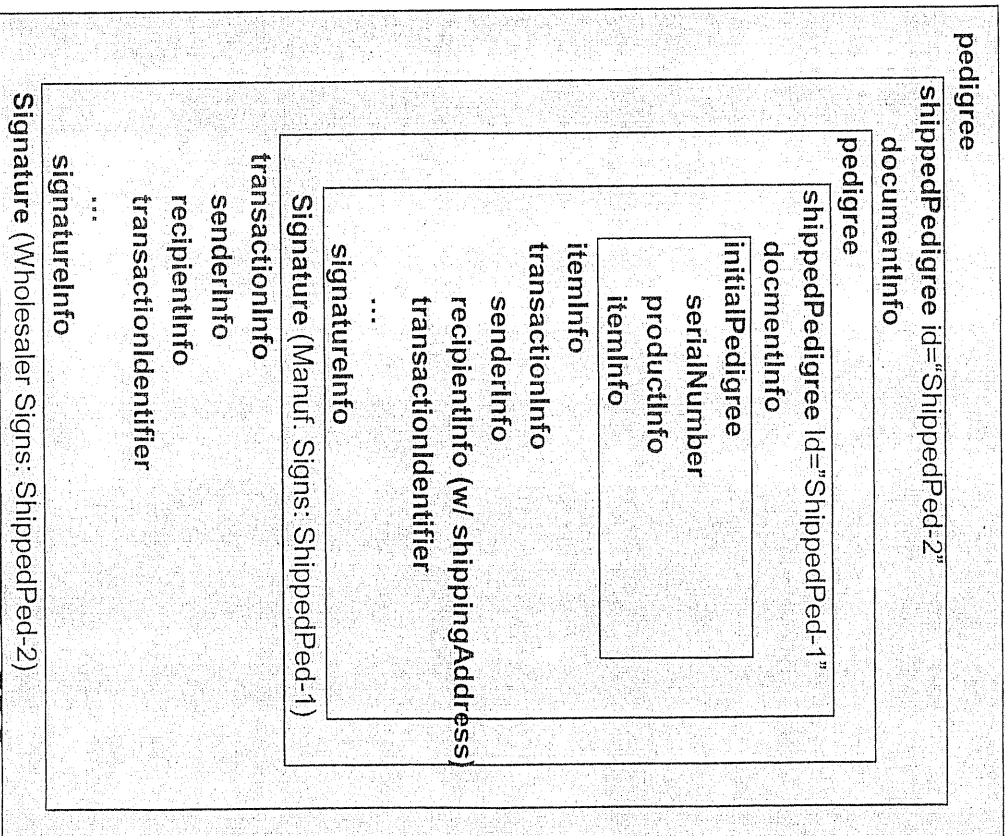   signatureInfo
  Signature (Wholesaler Signs: ReceivedPed-1a)

pedigree
  receivedPedigree Id="ReceivedPed-1b"
    documentInfo
    pedigree
      shippedPedigree Id="ShippedPed-1"
        docmentInfo
        initialPedigree
          serialNumber
          productInfo
          itemInfo
        itemInfo
          lot
          quantity (Qty shipped: 100)
        transactionInfo
          senderInfo
          recipientInfo
          transactionIdentifier
        ...
        signatureInfo
      Signature (Manuf. Signs: ShippedPed-1)
    receivingInfo
      dateReceived
      itemInfo
        lot
        quantity (Qty received: 25)
    signatureInfo
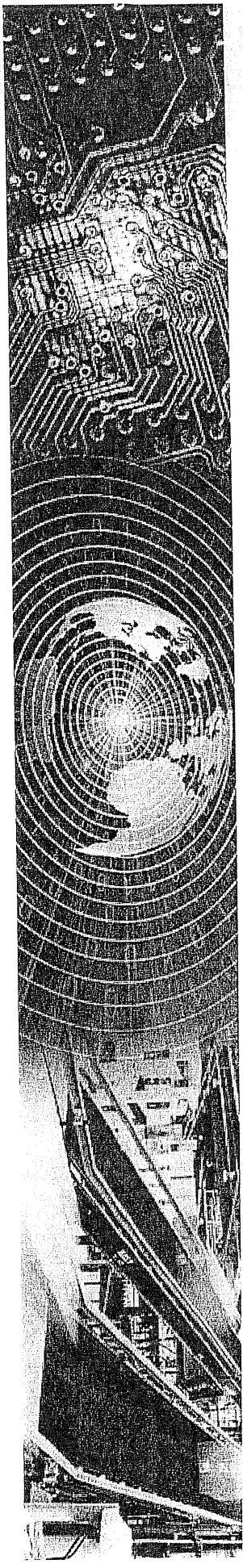 Signature (Wholesaler Signs: ReceivedPed-1b)
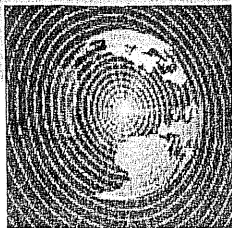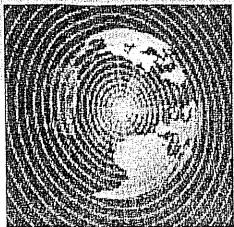
Sample Pedigree Forms

Pedigree Flow for a Manufacturer-initiated Drop Ship

The pedigree flow is described for a drop ship transaction brokered by wholesaler, where pharmacy purchases the product from the wholesaler, but the manufacturer ships the product directly to the pharmacy. In this scenario, the manufacturer initiates the start of the drop ship pedigree documenting the sales transaction from the manufacturer to the wholesaler with the shipping information indicating the direct shipment to the pharmacy. The wholesaler adds only the second part of the drop ship transaction to the pedigree documenting the sales transaction from the wholesaler to the pharmacy.

```
pedigree
  shippedPedigree id="ShippedPed-2"
    documentInfo
    pedigree
      shippedPedigree Id="ShippedPed-1"
        docmentInfo
        initialPedigree
          serialNumber
          productInfo
          itemInfo
        itemInfo
        transactionInfo
          senderInfo
          recipientInfo (w/ shippingAddress)
          transactionIdentifier
        ...
        Signature (Manuf. Signs: ShippedPed-1)
      signatureInfo
    transactionInfo
      senderInfo
      recipientInfo
      transactionIdentifier
    ...
    signatureInfo
    Signature (Wholesaler Signs: ShippedPed-2)
```

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Pedigree Scenario Walk Through

Pedigree Trace Scenarios

Scenario 1: This scenario depicts the pedigree flow for the sale of a serialized product from a manufacturer to a wholesaler, when the manufacturer initiates the pedigree. The wholesaler then sells and ships one of the product items to a pharmacy DC.

Scenario 2: This scenario depicts the sale of a non-serialized product from a wholesaler to a retail pharmacy DC, when no pedigree is provided by the manufacturer and the wholesaler initiates the pedigree.

Scenario 3: This scenario depicts the sale from a wholesaler to a retail pharmacy DC, when a paper pedigree is provided by the manufacturer and the wholesaler initiates the pedigree.

Scenario 4: The pedigree flow is described for a sale from a repacker to a wholesaler, where the repacker initiates the pedigree for a repackaged item. The repack pedigree contains the pedigree for the source product used to create the repack products

Scenario 5: This scenario depicts the kitting of several products and the subsequent sale from a kit manufacturer to a wholesaler.

Scenario 6: This scenario depicts the partial receipt of product for sale from a manufacturer to a wholesaler, when the manufacturer initiates the pedigree. It then includes another transaction from one wholesaler to another, which depicts the receipt of a pedigree without signing the pedigree on inbound receipt. The pedigree is subsequently signed on the next outbound transaction to the retail pharmacy.

Scenario 7: This scenario depicts the pedigree flow for the sale of a non-serialized product from a manufacturer to a wholesaler, when the wholesaler initiates the pedigree. The wholesaler then sells and ships the product to a pharmacy DC, then the pharmacy DC returns the product to the wholesaler. Then the wholesaler sells and ships the product to another pharmacy DC. This pharmacy DC also returns the product to the wholesaler.

GS1 EPCglobal
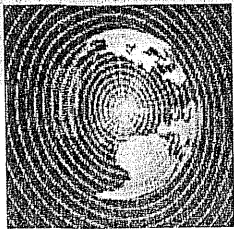
Pedigree Track Scenarios

The following are "Track" Scenarios and are <u>not supported</u> by the current Pedigree standard.

•**Scenario 8**: This scenario depicts the ability for a company to identify the location of all the units of a particular NDC/lot or a particular EPC at downstream trading partners that they have sold product to in order to support faster recalls.

•**Scenario 9**: This scenario depicts the ability for a company to see the aggregate inventory levels and product movement of all of a particular NDC/lot at downstream trading partners that they have sold product to in order to support more effective forecasting & replenishment.

GS1 EPCglobal
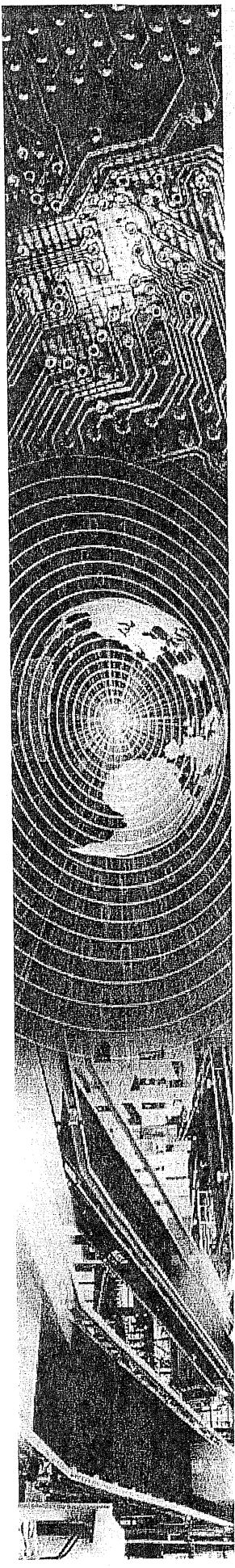
Follow-up Items

from California Board of Pharmacy
Pedigree review meeting

GS1 EPCglobal
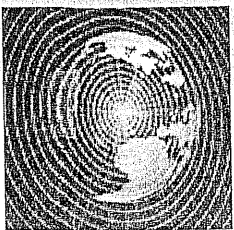
Pedigree Review Follow-up

1. Unit Dose Serialization

2. Partial Shipments

3. Drop Shipments

4. Signature and Certification of in-bound shipments

5. Return of saleable product to Mfgr by Whlsr and later resold by Mfg.

6. Pedigree status for intra-company transfers into CA.
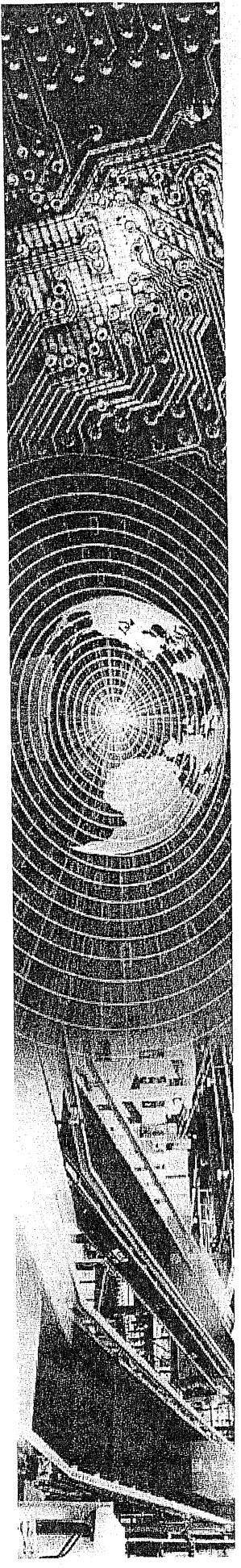
7. Voided Pedigrees

8. Inference
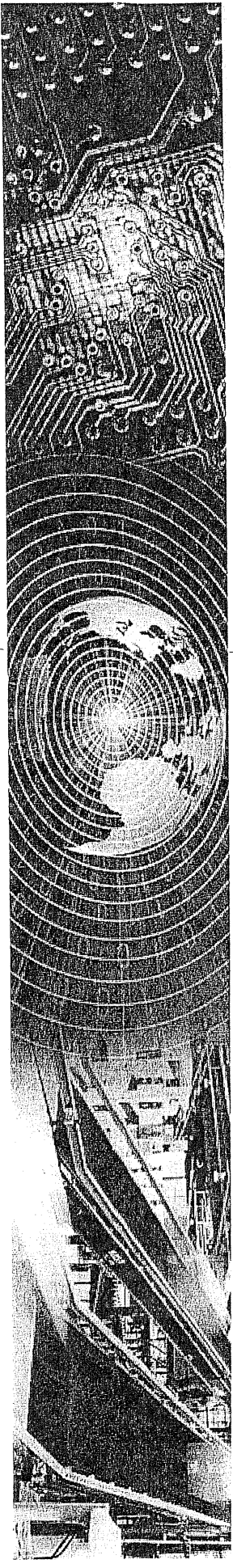
GS1 EPCglobal
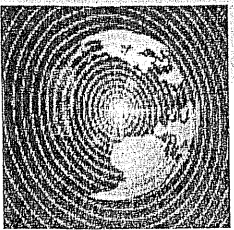
For more information on the Pedigree Messaging Standard

- Planned Web Seminars:

  - April 16 at 9:00 am Eastern
  - April 24 at 11:00 am Eastern
  - May 9 at 2:00 pm Eastern
  - May 15 at 2:00 pm Eastern

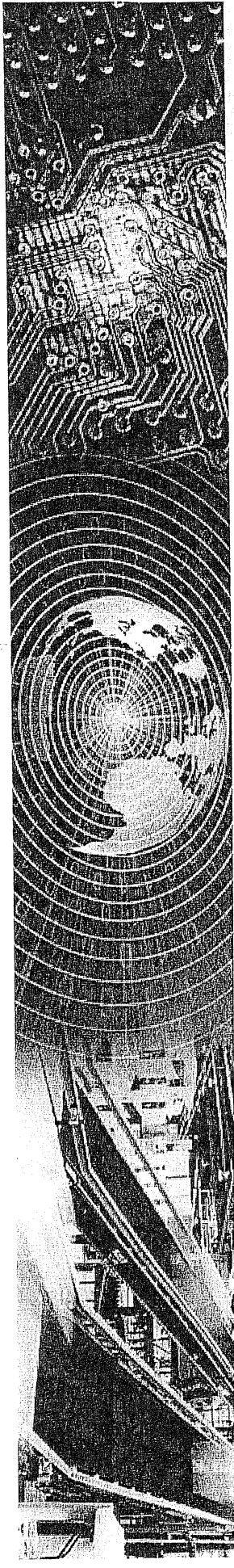To register for a Web Seminar, please contact Bob Celeste at:
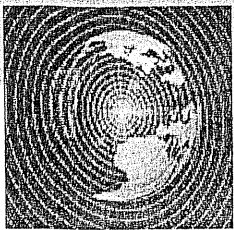
rceleste@epcglobalna.org

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Questions
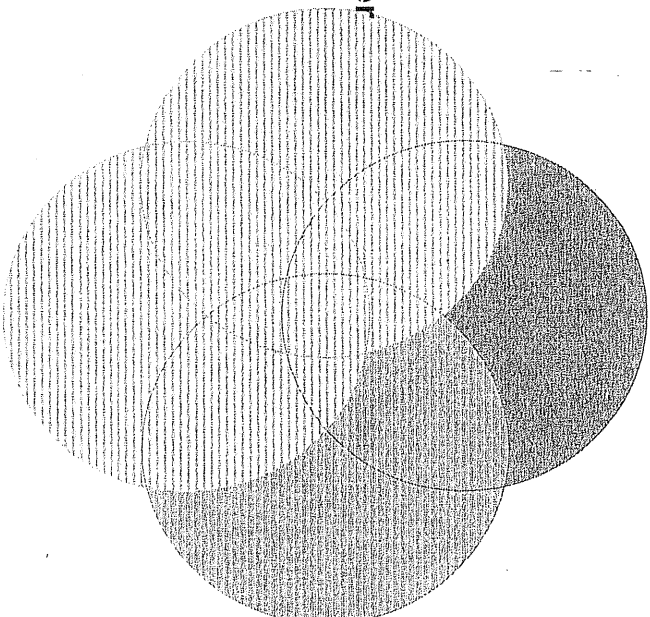
Additional Slides

Pedigree Related Terms

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Definitions

Physical Marking Carrier
(RFID, 2D Barcode,
Linear Barcode)

Drug
Pedigree

Product Identification (EPC)

Product
Serialization

40

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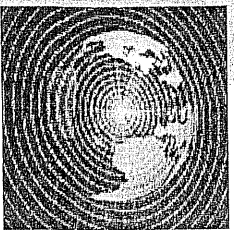
Definitions

Pedigree Serialization EPC RFID

The HEADER identifies the EPC version number, enabling different types and future revisions of EPC.

The EPC MANAGER is the name of the enterprise; typically the company responsible for maintaining the Object Class and Serial Number.

01.0037000.1234567.00000000

The OBJECT CLASS is the class of the product; usually the stock keeping unit or other object-grouping systems.

The SERIAL NUMBER is the unique object identifier.

More transistors than the processor in a 1985 IBM PC-AT. Lower power consumption than a honeybee's brain.

- **Pedigree:** The document, electronic or paper, which communicates the custody history for a particular medication.

- **Serialization:** A unique number assigned and affixed to a particular unit of item. Used to identify the particular bottle.
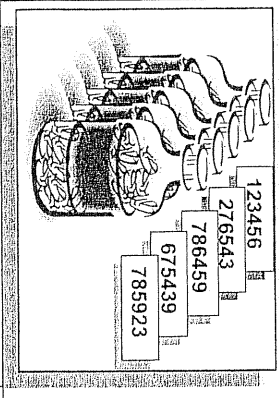
- **EPC:** Electronic Product Code – A globally and multi-industry acceptable identifier standardized by EPCglobal used to serialize items in many supply chains around the world.
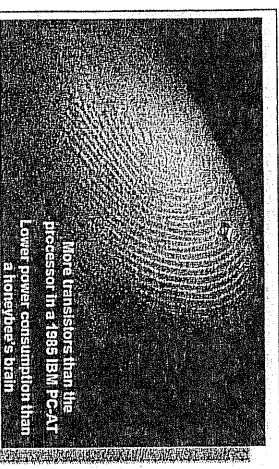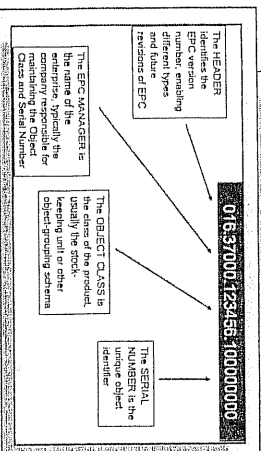
- **RFID:** The technology that can carry an EPC. Made up of a tag (computer chip), antennae, substrate
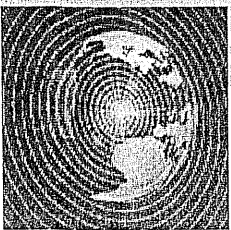
GS1 EPCglobal

The Future of Pedigree

- Continued use of the Pedigree Messaging Standard

- Investigating the use of the EPCglobal Network architecture to provide "Pedigree on Demand"

Document Based Pedigree
Passing the Pedigree through the supply chain

Track and Trace Data
Passing keys to pre-existing data

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